UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SKYLAR WILLIAMS, individually and on behalf of all others similarly situated, Plaintiff, v. GALDERMA LABORATORIES, L.P., Defendant.	Case No.: 1:24-cv-02222 Honorable Lindsay C. Jenkins

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT GALDERMA LABORATORIES, L.P.'S MOTION TO DISMISS

Dated: June 20, 2024

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INTRODUCTION

Galderma Laboratories, L.P. ("Galderma" or "Defendant") is a multinational skin care company based in Switzerland with locations around the world, including in the United States. Defendant is incorporated in Texas, with its U.S. headquarters located in Dallas. Defendant markets and sells its skin care products in the United States, including acne treatment products under its Differin line. This case specifically concerns Defendant's Differin products that contain the active ingredient benzoyl peroxide ("BPO") (hereinafter, "Differin" or the "Products").

Defendant's use of BPO as an active ingredient in the Products has resulted in a dangerous amount of benzene in the Products. Benzoyl peroxide has been shown to degrade into benzene, particularly at higher temperatures. *See* Class Action Complaint, ECF No. 1 ("Compl."), ¶¶ 24-25. Per the Department of Health and Human Services ("HHS"), benzene causes cancer in humans, and the Food and Drug Administration ("FDA") has recommended that BPO not be employed in manufacturing drug substances. *See id.* ¶ 21. Despite these warnings about benzene, Defendant, in manufacturing the Products, used BPO as an active ingredient, which it knew or should have known would inevitably degrade into benzene. At no point has Defendant labeled benzene an ingredient in Differin, and at no point were consumers warned about the presence of benzene in the Products. *See id*. ¶ 4.

Defendant's conduct flies in the face of both federal and state-level regulations. Defendant failed to comply with the FDA's current Good Manufacturing Practices ("cGMP") by allowing benzene to form in its Products. This failure of compliance with the cGMP renders Differin both "misbranded" and "adulterated" under federal law. *See id*. ¶ 60. Drugs that are misbranded or adulterated are legally worthless. Had Plaintiff and other purchasers of Differin been made aware of the presence of benzene prior to purchase, they would have paid a reduced price, or would not

have purchased the Product at all. *Id.* ¶¶ 4, 7, 47, 65. As a result, Defendant earned a profit by falsely labeling defective Products, in violation of consumer protection law.

Defendant argues that Plaintiff cannot bring her state-level claim because any state requirements that "are 'different from,' 'in addition to,' or 'otherwise not identical with' federal requirements" are prohibited under the FDCA. Defendant's Motion to Dismiss ("MTD") at 1. However, the requirements set forth in the Illinois Food, Drug and Cosmetic Act ("IL FDCA") are identical to federal labeling requirements. *See* Compl. ¶ 63. Thus, Illinois does not impose additional or differing requirements as Defendant claims. Defendant also attests that the degradation of BPO into benzene in Differin does not fit the meaning of "misbranding" and "adulteration." But Defendant's noncompliance with the cGMP *per se* renders its Products misbranded and adulterated. *See id*. ¶ 52. Defendant failed to manufacture the Products in accordance with the FDA's safety, identity, strength, quality, and purity standards, and then it labeled its' Products in a false and misleading manner by omitting benzene from the list of ingredients. Both actions violate federal regulations. Accordingly, the Court should deny Defendant's Motion to Dismiss.

BACKGROUND

A. The Risk of Benzene

The harm that exposure to benzene could cause in a human being has been known to the scientific community since as early as 1939, when a study in the *Journal of Industrial Hygiene and Toxicology* found that any long-term exposure to benzene is not safe for humans.[1] This finding

[1] F.T. Hunter, *Chronic Exposure to Benzene (Benzol). II. The Clinical Effects*, 21 J. Indust. Hygiene & Toxicology 331 (1939), https://www.cabidigitallibrary.org/doi/full/10.5555/19402700388.

was confirmed in 2010 with research that showed that there is no level of benzene exposure that is safe.[2] HHS found that benzene is a carcinogen, while the Center for Disease Control ("CDC") has said that benzene interferes with a person's red blood cell count and white blood cell count. *See* Compl. ¶¶ 21-22. Because of the severe risk that benzene exposure poses to human health, the FDA has recommended that it not be used at all in the manufacture of drug products. *See id* ¶ 29. If the inclusion of benzene is "unavoidable," then the FDA instructs that its concentration in the drug product **must** be restricted to a maximum of 2 parts per million ("ppm"). *See id* ¶ 30. Because there is a long history of acne cream production without the inclusion of benzene, it is clear that the use of benzene in Differin is not "unavoidable." Thus, there is no concentration of benzene that can be present in the Products if they are to comply with federal guidelines. Defendant, however, failed to ensure the Products' compliance with these federal regulations.

B. Benzene in Differin

Valisure LLC is a medical testing company that conducts independent analyses of medications to ensure their quality. Valisure's laboratory possesses International Organization for Standardization ("ISO") accreditation. In March 2024, Valisure published a study pertaining to the presence of benzene in BPO-based acne creams. Valisure tested 175 acne treatment creams, 99 of which used BPO, and 76 of which did not. *See* Compl. ¶ 41. Not one of the 76 acne medications lacking BPO that were tested by Valisure contained benzene. By contrast, nearly 95 percent of the products that used BPO were found to contain benzene. *See id*. ¶ 41. One of the products where benzene was detected was Differin 5% cleansing cream, manufactured by Defendant.

Defendant claims that Valisure's method of high-heat testing amounts to little more than

[2] Martyn T. Smith, *Advances in Understanding Benzene Health Effects and Susceptibility*, 31 ANN. REV. PUB. HEALTH 133 (2010), https://www.annualreviews.org/content/journals/10.1146/annurev.publhealth.012809.103646.

junk science. MTD at 3. Valisure's accreditation from ISO, an international organization that has issued over 25,000 standards across an array of highly sophisticated industries, surely stands for itself.[3] But even if Valisure's high-heat testing method was assumed to be questionable, that fact would be irrelevant, because Valisure's study found benzene in nearly 95% of BPO products tested without any temperature elevation. *See* Compl. ¶ 41. Differin 5% cleansing cream was one of these products.[4]

Plaintiff and other class members purchased Defendant's Products at full price under the assumption that the Products were free of harmful substances, such as benzene. Even though the Products contained benzene, its presence was disclosed nowhere on the Products' labeling, leading Plaintiff to incorrectly believe that the Products were benzene-free. *See id*. ¶ 88. Therefore, Plaintiff and other class members bargained for and paid full price for Products that are worthless due to Defendant's deceptive labeling practices.

ARGUMENT

A. Plaintiff's Claims are not Preempted

Whenever a preemption argument is raised, the starting presumption is that Congress did not intend to preempt state law, and the party arguing for preemption bears the burden of overcoming that presumption. *See Hendricks v. StarKist Co.*, 30 F.Supp.3d 917, 925 (N.D. Cal. 2014). This presumption against preemption is particularly strong in fields traditionally regulated by states. *See N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995). The regulatory fields of health and safety are among these traditional fields. *See*,

[3] *About ISO,* INT'L ORG. FOR STANDARDIZATION, https://www.iso.org/about (last visited June 18, 2024).

[4] In any event, the validity of Valisure's science is not at issue on a Rule 12(b)(6) motion to dismiss, which takes Plaintiff's allegations as true. Here, Plaintiff alleges that the Products contain benzene. *See*, *e.g.*, Compl. ¶¶ 3, 5.

e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

The Federal Food, Drug, and Cosmetic Act (FDCA) contains an clear language that only preempts states from enforcing laws relating to OTC drugs that are "different from or in addition to, or that [are] otherwise not identical with, a requirement under" the FDCA. 21 U.S.C. § 379r(a). Given this express preemption clause, a state-based claim is not preempted by federal law if it is a parallel claim, meaning the state-law requirements are identical to and do not exceed the federal requirements. *See Medtronic, Inc.* at 495. Since none of Plaintiff's claims are based on state-level requirements that exceed their federal counterparts, none of the claims should be dismissed on that account. On the contrary, Plaintiff's claims are rooted in Defendant's misbranding and adulteration of Differin as defined by the FDA's cGMP and other federal regulations, and it is those violations that form the entire basis of Plaintiff's state law allegations. *See* Compl. ¶ 63-64 (noting that Defendant's conduct violates the IL FDCA, which expressly adopts federal labeling requirements as its own).

The crux of Defendant's preemption argument here is that the requirements that Plaintiff claims Galderma violated go beyond what the FDA actually requires. Defendant claims that the only requirements that Galderma must adhere to are a 2020 Monograph released by the FDA and the general safety provisions of 21 C.F.R. § 330.1. MTD at 9. Although there is nothing explicit in these provisions about providing a benzene warning on BPO-based acne drugs, Defendant does not account for the full scope of requirements it must adhere to.

21 C.F.R. § 330.1 states that, in addition to the requirements of that section, over-the-counter drugs must **also** comply with the labeling requirements of 21 C.F.R. § 201.66. *See* 21 C.F.R. § 330.1(c)(1). That section states, in part, that the information on the label must include "a listing of the established name of each inactive ingredient." *Id.* at (c)(8). An inactive ingredient is

"*any* component other than an active ingredient." *Id.* at (b)(8) (emphasis added). The word "component" is not defined anywhere in the section.

Defendant points out that the word "component" does have a definition in 21 C.F.R. § 210, which states that a component is "any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product." Defendant urges the Court to apply that definition to 21 C.F.R. § 201.66, even though 21 C.F.R. § 210.3(a) lists only three other sections, Section 201 not among them, that the "component" definition applies to. It stands to reason, therefore, that the Section 210 definition of "component" should not apply to 21 C.F.R. § 201.66 because Section 210 says it does not. Had the rule makers wished to apply that definition, they would have listed Section 201 in 21 C.F.R. § 210.3(a). We are not, "under the guise of liberal construction," to read into the statute words that do not appear there. *Demitropoulos v. Bank One Milwaukee, N.A.*, 953 F. Supp. 974, 985 (N.D. Ill. 1997) (quoting *Lang v. Lang,* 467 N.W.2d 772, 777–78 (1991)). Moreover, Section 201 pertains to labeling requirements, whereas Section 210 and the listed sections in 21 C.F.R. § 210.3(a) pertain to the manufacturing of drugs, so the FDA would have good reason to keep the Section 210 definitions away from Section 201.

It is true that the Court took a different view on this point in *Barnes v. Unilever United States Inc.*, where the Section 210 definition was applied to Section 201. *See Barnes v. Unilever United States Inc.*, 2023 WL 2456385, at *7 (N.D. Ill. Mar. 11, 2023). Specifically, the *Barnes* Court made the determination that, although the plaintiff correctly pointed out the differences in subject matter between Sections 201 and Section 210, "she did not explain why this distinction is significant." *Id*.

But that difference is significant, especially when looking at the "component" definition as a whole. The entire definition of "component" under Section 210, which Defendant fails to quote

in full in its Motion to Dismiss, is "any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product." This full definition demonstrates that the FDA wanted the definition of "component" to be inclusive, not exclusive. The purpose of the definition, and the FDA's use of the word "intended," was to include those components that were intended to be used, even if they didn't make it into the final product. The manufacturing phase takes place prior to the drug's completion, and it is about the *process*, when different formulae and ingredients are still being considered and tweaked, and so it stands to reason that the FDA did not want materials initially included but later cast aside to be exempt from the regulation of drug manufacturing.

The labeling of a drug product is different. If manufacturing is about the process, labeling is about the final result. It is not about what materials were initially intended to be in the drug, but rather what materials are actually in the end product. It would not make sense for the FDA to apply the same definitions that apply to the manufacturing section to Section 201, its labeling section. Labeling and manufacturing are two completely separate and distinct processes with different considerations involved, and therefore need two completely different sets of requirements and accompanying definitions.[5]

Applying this reasoning, the Court should take the definitions of 21 C.F.R. § 201.66 on their own. The section defines "inactive ingredient" as "any component other than an active ingredient." Per Valisure's analysis, in Differin's case, this includes benzene. And as benzene is not listed as an inactive ingredient, Differin is misbranded under FDA regulations.

But regardless of the "component" definition the Court applies, the Products are still

[5] Indeed, if the requirements were intended to be the same, then the FDA could have just made a single section covering both labeling and manufacturing requirements. The FDA did not do so.

misbranded. Here, Plaintiff has, in essence, alleged that the Products contain a harmful, and undisclosed adulterant. Such state law claims find parallels in federal law, due to Defendant's failure to comply with the FDA's cGMP. Defendant argues that Plaintiff's claim that BPO degrades into benzene does not meet the definition of adulteration, MTD at 10, but as Defendant admits, any violation of the cGMP renders a drug adulterated, and Plaintiff does allege violations of specific cGMP's in her Complaint. *See* Compl. ¶¶ 53-55. In particular, Plaintiff alleges violations of 21 C.F.R. § 211.160, which states: "[t]here shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.160. Given that Defendant's Products contain the known carcinogen benzene, the Products do not have the "quality" or "purity" that Defendant purports they do. This amounts to a clear allegation of a violation of a cGMP, which in turn amounts to a claim of adulteration.

Defendant argues that this is not enough, that Plaintiff did not allege violations of the cGMP with enough specificity. But recent decisions say otherwise. In *McGee v. Johnson & Johnson*, 684 F.Supp.3d 371 (W.D. Pa. 2023), the Defendant argued that Plaintiff's "conclusory" allegations of cGMP violations was not enough to survive a motion to dismiss. The Court disagreed, ruling that, given the limited information available to the plaintiff pre-discovery, that the plaintiff's allegations of violation of specific cGMP's were enough to survive dismissal, and that their parallel nature with the FDCA precluded preemption. *See id.* at 381*; see also In Re: Chantix (Varenicline) Mktg., Sales Pracs. & Prods. Liab. Litig. (No. II)*, 2024 WL 2784234, at *20-21 (S.D.N.Y. May 28, 2024) (concluding the same).

Plaintiff thus states a valid claim that Defendant misbranded its Products by failing to list benzene as an inactive ingredient, in violation of federal labeling requirements. And Plaintiff also

separately states a valid claim for adulteration, by way of Defendant's violations of several cGMP's. Because Plaintiff claims legitimate federal violations, her state-level claims do not exceed what federal law requires, and therefore, are not preempted.

B. Plaintiff Has Sufficiently Alleged Her Consumer Protection Claims

1. Defendant's Safe Harbor Defense is Unavailing

Defendant argues that Plaintiff's ICFA claim and other state consumer protection claims should be dismissed due to ICFA's safe harbor provision precluding Plaintiff's ICFA claim. *See* MTD at 11. Defendant is mistaken. "The issue of defendants' compliance with the ICFA's … statutory exemptions is an affirmative defense to liability, not something that a plaintiff must prove." *Illinois v. McGraw-Hill Co*., 2013 WL 1874279, at *5 (N.D. Ill. May 2, 2013). Thus, resolution of the safe harbor defense is "not normally appropriate for a Rule 12(b)(6) motion." *Fields v. Alcon Labs., Inc*., 2014 WL 1041191, at *2 (S.D. Ill. Mar. 18, 2014).

Should the Court consider this defense at the pleadings stage, Defendant is not exempt from liability under "safe harbor" defense because the FDA never "specifically authorized" Defendant's conduct or the presence of benzene in the Products. 815 Ill. Comp. Stat. Ann. 505/10b; *See Vanzant v. Hill's Pet Nutrition*, 934 F.3d 730, 735 (7th Cir. 2019) (safe harbor did not apply where FDA "guidance [did] not specifically authorize the conduct alleged"); *see also Price v. Philip Morris, Inc*., 848 N.E.2d 1, 36 (2005) (Defendant's "mere compliance with the rules applicable to labeling and advertising is not sufficient to trigger the exemption created by section 10b(1)"). Defendant's conduct is not authorized by the laws of Illinois or the United States, and in fact, is expressly prohibited by them.

Defendant claims (1) that the FDA "authorizes" Galderma to sell the Products without any disclosure of the potential presence of benzene and (2) that Galderma's labeling complies with the

FDA monograph for acne products. *See* MTD at 12. But as described above, the FDA regulations require Defendant to include benzene as an inactive ingredient on every product bottle. *See, supra*, Argument § B2; *see also Al Haj v. Pfizer Inc.*, 338 F. Supp. 3d 741, 756-57 (N.D. Ill. 2018) (distinguishing *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934 (7th Cir. 2001) and ruling against defendant's contention that the safe harbor provision required dismissal in case regarding misleading label). Moreover, the Product is misbranded under the FDCA since the Products' labeling fails to reveal that the Products contain benzene. 21 U.S.C. § 352(a)(1); Compl. ¶ 24; In *re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2021 WL 100204, at *3. (a drug is "misbranded" if, among other things, "(1) its labeling is false or misleading [or] (2) if the labeling does not contain the proportion of each active ingredient"). The absence of this disclosure conveys to consumers that it is not possible that benzene may be in the Products, which independent third-party testing has proved demonstrably false. Compl. ¶ 42; 21 C.F.R. § 740.1 ("The label of a cosmetic product shall bear a warning whenever necessary or appropriate to prevent a health hazard that may be associated with the product."). Likewise, a drug is "adulterated" if, among other things, "it consists in whole or in part of any filthy, putrid, or decomposed substance." 21 U.S.C. § 351(a)(1). The mere presence of benzene renders the product both adulterated and misbranded under the FDCA. *Id.* The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a); *see also* 410 ILCS 620/14 (adopting FDCA labeling requirements). Manufacturers, like Defendant, are bound by these requirements at all phases of the design, manufacture, and distribution chain.

Accordingly, since Defendant's conduct is prohibited—rather than permitted—under federal law, the ICFA's safe harbor provision does not apply and Defendant is not exempt from

liability under the "safe harbor" defense. *See Barnes*, 2022 WL 2915629, at *3 (signaling ICFA safe harbor likely does not apply where plaintiff alleged "federal law, specifically the Food Drug, and Cosmetic Act, precludes introduction into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded") (cleaned up); *see also Jamison v. Summer Infant (USA), Inc.*, 778 F. Supp. 2d 900, 909 (N.D. Ill. 2011) (FCC labeling regulations did not "specifically authorize" the omission of material facts from packaging of video monitor). Likewise, Defendant's other state consumer safe harbor defenses do not prosper "for the same reason that ICFA's safe harbor provision" does not apply. *Bojko v. Pierre Fabre USA Inc.*, 2023 WL 4204663, at *9 (N.D. Ill. June 27, 2023); *see also Price*, 848 N.E.2d at 36 ("Conduct is not specifically authorized merely because it has not been specifically prohibited.").

2. Plaintiff Has Adequately Alleged that Defendant Knew or Should Have Known that the Products Contained Benzene

The ICFA requires that for an omission to be actionable, it must be about a material fact that the defendant knew and concealed or failed to disclose, intending for others to rely on this omission "where a buyer would have acted differently knowing the information." *Kinman v. Kroger Co.*, 604 F. Supp. 3d 720, 728 (N.D. Ill. 2022). Plaintiff's allegations regarding intent are sufficient at the pleading stage because allegations concerning "intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); *see Freeman v. MAM USA Corp.*, 528 F. Supp. 3d 849, 864 (N.D. Ill. 2021) (arguments as to the adequacy of the allegations of intent were "prematurely raised at the pleading stage").

Contrary to Defendant's argument, Plaintiff alleges extensive (and plainly sufficient) facts in support of her claim that Defendant knew or should have known that its Products either contained or risked containing benzene. *See* Compl. ¶ 66 ("As seller of an OTC drug product, Defendant had and has a duty to ensure that its Products did not and do not contain excessive (or

any) level of benzene, including through regular testing, especially before injecting the Products into the stream of commerce for consumers to use on their bodies. But based on Valisure's testing results, Defendant made no reasonable effort to test its Products for benzene or other impurities."); *id.* at 77 ("If Defendant had fulfilled [its] quality assurance obligations, Defendant would have identified the presence of the benzene through routine and required testing"); *id.* at 78 ("[H]ad Defendant adequately tested its Products for benzene and other carcinogens and impurities, it would have discovered that its Products contained benzene—even at levels above the FDA's limit (to the extent even applicable)"); *id.* at 79 ("Defendant also knew or should have known about the carcinogenic potential of benzene because it is classified as a Group 1 compound by the World Health Organization and the International Agency for Research on Cancer . . . ."). Defendant should therefore have been on high alert to test its Products for the presence of benzene. And because Defendant is a retailer industry leader for the Products, Plaintiff and reasonable consumers rely on Defendant's product representations, including any lack thereof.

Plaintiff thus sufficiently alleges that Defendant (i) failed to disclose the presence of benzene in its Products, which was a material omission, (ii) falsely represented that the Products only contained the listed active and inactive ingredients, and that benzene was not among those listed, and (iii) failed to adequately test and identify the Products for benzene. *See*, *e.g.*, Compl. at ¶¶ 5, 7, 44, 125; *Barnes*, 2022 WL 2915629, at *3 ("[A]llegations that Unilever put adulterated and therefore dangerous products into the marketplace without adequate testing or screening … are sufficient to state a claim for an unfair practice violative of the ICFA."). Ultimately, whether Defendant knew of the presence of benzene in its Products, and when it became aware of it, is fundamentally "a question of fact to be determined by the trier of fact." *White v. DaimlerChrysler* Corp., 856 N.E.2d 542, 550 (Ill. App. Ct. 2006). The exact details of what Defendant knew and

when would likely be in Defendant's exclusive knowledge and can be explored in discovery.

3. Plaintiff's Other Consumer Protection Statue Claims Should be Upheld.

Here, Defendant does not provide any additional argument regarding how other state's consumer protection claims differ from those of Illinois, or why application of the safe harbor defense comports with the jurisprudence of these states. MTD at 12. Instead, Defendant relies entirely on its argument against Plaintiff's ICFA claim. *Id.* Accordingly, for the same reason that Defendant's argument against Plaintiff's ICFA claim fails, this argument fails as well. *See Bojko*, 2023 WL 4204663, at *9 ("Therefore, for the same reasons that the ICFA's safe harbor provision did not warrant dismissal at this stage, the other States' safe harbor provisions do not warrant dismissal either."). As discussed at length herein, Plaintiff has adequately pled the Products are both adulterated and misbranded under the FDCA. Compl. ¶¶ 48-62, 76, 80-81. Further, in *Bojko*, the Court refused to dismiss claims under consumer fraud acts from other states because "the best course is to defer this issue to the class certification stage". *Id.* at *3. *See, e.g., Shirley v. Reynolds Consumer Prods., LLC*, 2022 WL 13831598, at *3 (N.D. Ill. Oct. 21, 2022) (collecting cases and deferring issue of plaintiff's standing to bring claims on behalf of class members in other states to the class certification stage); *Muir v. Nature's Bounty (DE), Inc.*, 2018 WL 3647115, at *8 (N.D. Ill. Aug. 1, 2018) ("In light of the growing weight of authority that treats 'disjunctures' between a class representatives' claims and those of absent class members as a problem to be analyzed under the rubric of Rule 23, rather than the doctrine of statutory standing, the court will do the same here." (cleaned up)); *see also Freeman v. MAM USA Corp.*, 528 F. Supp. 3d 849, 859 (N.D. Ill. 2021) (declining to dismiss multi-state class claims on standing grounds, noting that "[w]hat MAM is really challenging is whether Freeman (or, actually, any Illinois resident who bought pacifiers only in Illinois) can satisfy the Civil Rule 23 class-certification requirements as applied to a

nationwide and multi-state class"). Likewise, the Court should defer this issue to the class certification stage.

Further, the same is true of Defendant's argument that "[b]ecause Plaintiff has not and cannot state a claim under the ICFA, *see supra* at pp. 11–14, she cannot represent a multi-state class under other states' consumer protection laws[.]" MTD at 14. Here, Defendant incorporates, by reference, its argument that Plaintiff has not pled knowledge with sufficient particularity. *Id.* The argument regarding Defendant's knowledge is incorrect for the same reason as set forth above: that the Complaint alleges that Defendant knew it failed to test for safety, numerous allegations that Defendant knew or should have known about the benzene risk posed by its Products and Defendant put adulterated and misbranded products into the stream of commerce. Compl. at ¶¶ 48-62, 66, 76-81.

4. Plaintiff's Massachusetts' Pre-Suit Notice.

"[Chapter 93A 9(3)] clearly excuses the plaintiff from serving a demand letter if the prospective respondent either lacks a place of business in Massachusetts or does not keep assets in Massachusetts." *Moronta v. Nationstar Mortg., LLC*, 64 N.E.3d 1287, 1290 (2016). Defendant has provided evidence that they maintain a place of business within Massachusetts. *See* MTD Ex. A. Due to this new information, Plaintiff, at this time, requests from this Honorable Court leave for 30 days to provide the required Pre-suit Notice (Mass. Gen. Laws ch. 93A, § 9(3)) to Galderma's Massachusetts office and leave to amend the complaint to reference the proper record of events. "In considering a motion for leave to amend…the trial court must first consider whether the proposed new claims are futile, that is, whether they would be subject to dismissal for failure to state a claim." *MacNeill Eng'g Co. v. Trisport, Ltd.,* 59 F. Supp. 2d 199, 201 (D. Mass. 1999) (quoting *Smith v. Mitre Corp.,* 949 F.Supp. 943, 945 (D.Mass.1997) (Lindsay, J.)). Absent a

showing of futility, leave should only be denied if the amendment would be overly prejudicial. *Id.; see also Tarpey v. Crescent Ridge Dairy, Inc.,* 713 N.E.2d 975, 983 (1999) (allowing the plaintiff to amend complaint and add claim under Chapter 93A where demand letter was sent after suit had commenced). Hence, Plaintiff requests leave to amend to cure her pre-suit notice deficiency given Plaintiff only recently learned of new information that requires pre-suit notice and an amendment would not be prejudicial to Defendant.

C. Plaintiff's Unjust Enrichment Claim Should be Upheld

Defendant purports that Plaintiff's unjust enrichment claim "is based on the same exact Allegations" as the consumer protection claims and therefore must be dismissed. *See* MTD at 15. But the Federal Rules of Civil Procedure explicitly permit a plaintiff to plead a claim in the alternative. *See* Fed. R. Civ. P. 8(d)(2). And should the Court find that Plaintiff's unjust enrichment claim is dependent on the consumer fraud claims, Plaintiff has adequately pled those cause of actions. *Supra*, Argument § B1-2. And regardless, "there is authority supporting the opposition that unjust enrichment may in appropriate circumstances serve as a stand-alone claim under Illinois law." *Barnes*, 2022 WL 2915629 at *2 (citing *Cleary v. Philip Morris Inc.*, 656 F.3d 511 (7th Cir. 2011)). Accordingly, the Court should not dismiss Plaintiff's claim for unjust enrichment.

Dated: June 20, 2024

Respectfully submitted,

/s/ J. Hunter Bryson

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CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of June, 2024, I caused a true and correct copy of the foregoing notice to be filed with the Clerk of the Court for the Northern District of Illinois via the Court's CM/ECF system, which will send notification of such filing to the counsel of record in the above-captioned matter.

/s/ J. Hunter Bryson
J. Hunter Bryson